

## **REMARKS**

In the Office Action dated November 4, 2008, all of the pending claims were finally rejected. More specifically, claims 12-19, 21 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2002/0179166 to Houston et al. (Houston). Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in light of U.S. Patent No. 5,733,327 to Igaki et al. (Igaki). Claims 1, 3-6 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of U.S. Patent No. 6,569,191 to Hogan. Finally, claims 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Hogan and in further view of U.S. Patent No. 5,484,411 to Inderbitzen et al. (Inderbitzen).

Applicants are herewith filing a Request for Continued Examination and are presenting amended claims. For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

### **Independent Claim 12 and its Dependent Claims 1, 3-6, 9, 10, 13 and 15-23**

Independent claim 12 and its dependent claims 13 and 15-19, 21 and 23 were rejected as being unpatentable over Houston. It was stated that Houston discloses a stent 300 having an expanded configuration with a helical center line and a helix angle of 8°, which is within the claimed range of less than or equal to 65°. It was admitted that Houston fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing. However, it was asserted in the Office Action that it

would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

First, as to Figure 4A of Houston, Houston fails to disclose a stent which has a collapsed configuration and an expanded configuration, as recited in pending claim 12. As to Figure 4A, the "wire mesh 6 [is] fitted over part of the length of a graft 3" as explained in paragraph 50 of Houston. Thus, Figure 4A clearly shows an external scaffold which is intended to fit around the outside of a vessel, in this case, the graft 3. Indeed, that is all which is shown in Figure 4A of Houston. Claim 12 is novel over Figure 4A because it is directed toward a stent for insertion into a fluid conduit and for expansion in that conduit from a collapsed condition of the stent into an expanded condition of the stent. There is no collapsed condition shown for the wire mesh 6 in Houston, nor is there an expanded condition thereof discussed. Obviously, the wire mesh 6 in Figure 4A of Houston is not expanded from a collapsed condition thereof, since it is meant to be "fitted over" a fluid conduit. Put another way, Houston's wire mesh 6 supports a fluid conduit from the outside, whereas the stent recited in claim 12 supports a fluid conduit from the inside. Therefore, the anticipation rejection of claim 12 over Houston should be withdrawn.

Moreover, Figure 4A of Houston does not disclose a stent which has a helical center line. Reference is also made to the applicant's comments in connection with the amendment dated August 25, 2008 and its description of Houston. For the sake of

brevity, that description will not be repeated here. To provide a helical flow pattern, an internal spiral formation consisting of radially inwardly projecting vane members 104 (see Figures 10 and 12) are taught by Houston. But the tubes and stents of Houston do not have a helical center line which meets the limitations recited in pending claim 12.

Another figure in Houston, Figure 5, does show a helical center line for a coiled mesh structure 11. However, this mesh structure is also an external scaffold, as is described in paragraph 51 of Houston. Therefore, claim 12 is also novel over Figure 5 because it is directed toward a stent for insertion into a fluid conduit of a human or animal body. In other words, Figure 5 of Houston, like Figure 4A, fails to disclose a stent for insertion when it is in a collapsed condition and which can be moved to an expanded condition. This cannot be done with the structures shown in Houston, since they are only external scaffolds. In sum, Houston fails to disclose a stent which is expandable from a collapsed condition to an expanded condition, as recited in claim 12.

Applicant hereby amends independent claim 12 to add to it the subject matter of former claim 14. That subject matter recites that the stent, in the expanded condition, is substantially free of ribs which would project into the flow lumen of the conduit. In paragraph 5, on page 3 of the Office Action, it was asserted regarding claim 14 that Houston discloses a stent that is substantially free of ribs which would interfere with the flow lumen in its expanded condition. The Office Action referred to Figure 4A of Houston. The liabilities of Houston have been discussed previously.

Applicant has recently been made aware of two U.S. Patent Publications which are listed in the enclosed IDS. As it happens, both of these documents, U.S. Patent Publication 2006/0124187 and 2006/0047344, disclose conduits with internal ribs which

project into the flow lumen of the conduit. So, too, does the design shown in Figure 9B of Houston. Applicant notes that amended claim 12 patentably defines over the newly cited documents because claim 12 recites that the stent, in the expanded condition, is substantially free of ribs which would project into the flow lumen of the conduit. Moreover, it would not have been obvious to a person of ordinary skill in the art at the time the claimed invention was made that the desired swirl flow can be achieved without the use of ribs projecting into the flow lumen, as taught in Houston and in the two newly cited references. Therefore, claim 12 is in condition for allowance over all of the art of record.

Dependent claims 13, 15, 17-21 and 23 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also in condition for allowance over not only Houston, but also the remainder of the art of record.

As to claim 16, on page 3 of paragraph 7, it is asserted in the Office Action that Houston discloses a stent having a circular cross section and reference is made to Figure 4A. However, the cross section of Figure 4A is clearly disclosed as triangular in paragraph 50 of the Houston specification (“...mesh 6 imposes on graft 3 a shape which is approximately triangular.”). Therefore, claim 16 is also in condition for allowance.

Dependent claim 20 was rejected as being unpatentable over Houston, with the argument that a stent comprising a pharmaceutical coating is unpatentable over Houston because it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Houston with a coating as shown in Igaki. However, even the combination of Houston and Igaki neither teaches

nor discloses the subject matter recited in claim 20. More particularly, there is no disclosure in either Houston or Igaki of a stent which is insertable in a collapsed condition and can be expanded into an expanded condition within a fluid conduit and which stent in the expanded condition is substantially free of ribs that would project into the flow lumen of the conduit. Therefore, claim 20 also patentably defines over the asserted combination of Houston and Igaki, as well as the remainder of the cited art.

Dependent claims 1, 3-6 and 22 were rejected as being unpatentable over Houston in view of Hogan. It was contended in paragraph 15 of the Office Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided longitudinal extension resistance to the Houston stent as taught by Hogan in order to increase radial expansion to obtain a desired final diameter.

However, dependent claims 1, 3-6 and 22 also recite a stent which in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit and, generally, a stent which has an expanded condition and a collapsed condition, in which collapsed condition it is inserted into a human or animal body. As noted previously, there is no teaching or disclosure of such a stent in Houston. Moreover, there is no teaching or disclosure of such a stent in even the applied combination of Houston and Hogan. Therefore, dependent claims 1, 3-6 and 22 are also in condition for allowance over the applied combination of references, as well as the remainder of the art of record.

Dependent claims 9 and 10 were rejected over a three-way combination of Houston, Hogan and Inderbitzen. In this regard, it was stated that Houston discloses all of the limitations with the exception of a balloon expandable stent. Hogan was said to

teach a balloon expandable stent which radially expands the stent. Inderbitzen was said to teach an expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall extending from the distal to the proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting expansion of the balloon along a longitudinally extending spiral path. It was asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of Houston and Hogan with a helical portion as taught by Inderbitzen in order to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to insure dilation.

As mentioned previously, Houston fails to disclose a stent which is expandable from a collapsed condition to an expanded condition. Therefore, the purported combination of Houston, Hogan and Inderbitzen fails, as there is no reason to use the Inderbitzen expandable balloon or the Hogan balloon in connection with Houston's conduit 6 that is positioned over the exterior surface of a graft 3. In fact, Inderbitzen's balloon 12 would interfere with the positioning of the Houston conduit 6 over the graft 3. Obviously, two items -- the Inderbitzen balloon 12 and the Houston graft 3 -- cannot be in the same location (inside the Houston conduit 6) at the same time. The same is true of Hogan's balloon 107. Therefore, it is respectfully submitted that claims 9 and 10 also patentably define over the asserted combination of references, as well as the remainder of the cited art.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

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